



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0596]

Lung Cancer Patient-Focused Drug Development; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for lung cancer. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of lung cancer on daily life as well as the available therapies for lung cancer.

DATES: The public meeting will be held on June 28, 2013, from 8:30 a.m. to 12:30 p.m.

Registration to attend the meeting must be received by June 19, 2013 (see SUPPLEMENTARY INFORMATION for instructions). Submit electronic or written comments by July 29, 2013.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security checks will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the complete agenda and additional meeting background material approximately 5 days before the meeting at

<http://www.fda.gov/Forindustry/UserFees/PrescriptionDrugUserFee/ucm353273.htm>.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301-796-0684, FAX: 301-847-8443, email:

graham.thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected lung cancer to be the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments made as part of the reauthorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Public Law 112–144). The full set of performance commitments is available on the FDA Web site at

<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>.

FDA has committed to obtaining the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a document (78 FR 21613) in the Federal Register that announced the disease areas for meetings in fiscal years (FY) 2013 to 2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, document to develop the list of disease areas. Public comment on the Agency's proposed criteria and potential disease areas was gathered through a Federal Register document for public comment that was published on September 24, 2012 (77 FR 58849), and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a public process for determining the disease areas for FY 2016 and 2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will gather patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. Lung cancer is a disease caused by uncontrolled growth of

abnormal cells in the tissues of the lung, usually in the cells lining air passages. Lung cancer cells can spread (metastasize) to almost any other part of the body, such as to the brain or to bones. Available therapies for management of lung cancer falls into two main categories: therapies to reduce or control the spread of disease (including surgery, radiation therapy, conventional chemotherapy, and targeted therapies), and supportive care therapies to improve or manage symptoms of the underlying condition (lung cancer) or the side effects of cancer treatments. FDA is interested in patients' perspectives for the two main types of lung cancer (small-cell and non-small cell lung cancer) on the importance of disease symptoms, benefits of treatment approaches, and possible cancer treatment side effects.

The draft questions that will be asked of patients and patient stakeholders at the meeting are provided in the paragraphs that follow. For each of these topics, a brief initial patient panel discussion will begin the dialogue and will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through the public docket (see ADDRESSES).

Topic 1: Disease symptoms and daily impacts that matter most to patients

1. For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?
2. Of all the symptoms that you experience because of your lung cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)

3. Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of lung cancer? (Examples may include sleeping through the night, climbing stairs, household activities.)

Topic 2: Patients' perspectives on current approaches to treating lung cancer

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.

1.1 What do you consider to be the most significant downsides of these treatments?

(Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)

1.2 How do these downsides affect your daily life?

2. What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).

2.1 What specific symptoms do your treatments address?

2.2 How well do these treatments manage these symptoms?

2.3 Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?

3. When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?

4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:

4.1 What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)

4.2 How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite fatigue, diarrhea, rash.)

4.3 How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)

B. Attendance and/or Participation in the Meeting

If you wish to attend this meeting, visit <http://patientfocusedlungcancer.eventbrite.com>. Please register by June 19, 2013. Those who are unable to attend the meeting in person can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Graham Thompson (see FOR FURTHER INFORMATION CONTACT) at least 7 days

before the meeting. More information will be posted on the meeting Web site at least 5 days before the meeting date.

Patients who are interested in presenting comments as part of the initial panel discussions should indicate in their registration which topic(s) they wish to address. They will be asked to send a brief summary of responses to the topic(s) questions via email to

PatientFocused@fda.hhs.gov. Panelists will be notified of their selection soon after the close of registration on June 19, 2013. FDA will try to accommodate all patients and patient advocate participants who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the Web cast, are invited to provide electronic or written responses to any or all of the questions pertaining to Topics 1 and 2 to the Division of Dockets Management (see ADDRESSES). Comments may be submitted until July 29, 2013.

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.